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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. <i>26</i>
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

20
04/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/210,031

Applicant(s)

Lorincz

Examiner

Stephen Siu

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 23 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other _____

DETAILED ACTION

This is in response to Applicant's response amendment received March 23, 2001 (paper number 19).

The provisional statutory type (35 U.S.C. 101) double patenting rejection of claims 1-11 and 15-19 as cited in the prior office action mailed October 31, 2000 (paper number 15) is withdrawn in view of applicant's amendments and arguments.

The rejection of claims 2-12, 15-18 and 20 under 35 U.S.C. 102(e) as being anticipated by Dunphy as cited in the prior office action mailed October 31, 2000 (paper number 15) is withdrawn in view of applicant's amendments and arguments.

The rejection of claims 21-23 under 35 U.S.C. 103(a) as being unpatentable over Wainwright in view of Dunphy as cited in the prior office action mailed October 31, 2000 (paper number 15) is withdrawn in view of applicant's amendments and arguments.

The following action contains rejections of claims previously reported as allowable. The indicated allowability of claims 13 and 14 is withdrawn in view of newly discovered references (see below) and further careful consideration of the case. Rejections are based on the newly cited references that follow as well as further detailed consideration of the merits of the case. Great care has been exercised in authorizing the following rejections and issues. Of note, the primary examiner has carefully reviewed the facts of the case and has approved the present action.

The following issues are noted:

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 15-19, 29-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 and 16-20 of copending Application No. 09/598,571. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a medium comprising a cross-linking agent that is an aldehyde fixative or formaldehyde or glutaraldehyde. Application 09/598,571 recites a medium comprising a fixative. The generic claim of Application number 09/598,571 dominates the species claim of the instant application..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The rejection of claims 20-27 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-28 of

copending Application number 09/598,571 as cited in the prior office action mailed October 31, 2000 (paper number 15) is maintained for reasons of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The rejection of claims 1-4 under 35 U.S.C. 102(e) as being anticipated by Dunphy (US Pat No. 5679333, 10/21/97, filed 10/25/96) as cited in the prior office action mailed October 31, 2000 (paper number 15) is maintained. Applicant's arguments filed March 23, 2001 (paper number 19) have been fully considered but they are not persuasive. Applicant has amended the claim to recite the limitation that the cross-linking agent is an aldehyde comprising about 1% to about 15% of the medium and states that Dunphy supposedly does not teach a composition containing the added limitation. However, Dunphy teaches a medium containing a preservative, an anti-degradation agent and a cross-linking agent wherein the cross-linking agent is an aldehyde (i.e. ethanedial) comprising 14% v/v (col.7, lines 1-10). Thus, the composition as taught by Dunphy meets the limitations of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-11, 15-20, 24-27 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunphy (US Pat No. 5679333, 10/21/97, filed 10/25/96) in view of Hurley (US Pat 5256571, 10/26/93, filed 5/1/91).

Dunphy discloses a preservation fluid containing a preservative, an anti-degradation agent and a cross-linking agent wherein the crosslinking agent is an aldehyde comprising about 1% to about 15% of the medium as described above. The solution is disclosed as a tissue fixative for use in the histology field (col.6, lines 9-11). Dunphy further discloses a cell preservation fluid containing 3.75% cross-linking agent (ethanedial) and teaches the effectiveness of the solution at preserving tissue samples for histological study and evaluation (col.7, lines 60-63 and col.8 lines 1-10).

Dunphy does not disclose the solution as containing an alcohol or buffer.

Hurley discloses a cell preservative solution for use in the histology field, in particular, for preservation of cells for cytological analysis. The solution contains alcohol (most preferably, ethanol) and a buffer that maintains the pH between 4 and 7 (col.2, lines 11-21). Hurley teaches that the alcohol-buffer constituent maintains cell DNA integrity and retains the detail of the cell nucleus for subsequent cytological staining and analysis (col.3, lines 30-33 and lines 4-9) and also teaches the use of EDTA (an anti-degradation agent) to prevent clumping (col.2, lines 15-17 and col.3, lines 54-58).

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Hurley further discloses the solution as having additional use as a cell preservative by killing pathogens (col.4, lines 16-17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a cell preservation fluid useful in the histology field and containing the elements as taught by Dunphy and to further improve the solution by adding an alcohol (ethanol) – buffer constituent because doing so would maintain the cell DNA integrity and retain the detail of the cell nucleus for subsequent cytological staining and histological analysis as taught and demonstrated through the teachings of Hurley. One of ordinary skill in the art would have been further motivated to include EDTA in the solution as EDTA prevents clumping in solution as demonstrated through the teachings of Hurley. Therefore, one of ordinary skill in the art would have been motivated to utilize an ethanol-buffer constituent at a pH between 4 and 7 with the cell preservation fluid for use in the histology field to preserve DNA integrity and maintain nuclear detail with a reasonable expectation of success.

Claims 13-14, 29-30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunphy (US Pat No. 5679333, 10/21/97, filed 10/25/96) in view of Hurley (US Pat 5256571, 10/26/93, filed 5/1/91) as applied to claims 5-11, 15-20, 24-27 above, and further in view of Harrison (US Pat No. 4578282, 3/25/86, filed 1/4/85).

Dunphy in view of Hurley teach a cell preservation fluid as described above.

Dunphy in view of Hurley does not teach the cell preservation fluid as containing glutaraldehyde.

Harrison discloses a fixative composition for histological or cytological preparations containing a C1-C10 alcohol and water wherein glutaraldehyde is added for a greater degree of complexing fixation for tissue and other proteinaceous preparations (col.3, lines 3-7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a cell preservation medium as per the teachings of Dunphy in view of Hurley as described above and to further add glutaraldehyde because doing so would provide a greater degree of complexing fixation for tissue and other proteinaceous preparations as disclosed through the teachings of Harrison. Thus, one of ordinary skill in the art would have been motivated to provide such a cell preservation medium with a greater degree of complexing fixation containing glutaraldehyde with a reasonable expectation of success.

Claims 21-23, 28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunphy (US Pat No. 5679333, 10/21/97, filed 10/25/96, Hurley (US Pat 5256571, 10/26/93, filed 5/1/91) and Harrison (US Pat No. 4578282, 3/25/86, filed 1/4/85) as applied to claims 5-11, 13-20, 24-30 and 32 above, and further in view of Wainwright (US Pat No. 5370128, 12/06/94).

Dunphy, Hurley, and Harrison teach a cell preservation fluid as described above but do not teach an article of manufacture comprising a container, a lid and a brush for preserving a cell sample.

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Wainwright discloses an article of manufacture comprising a container, a lid fitting the container, and a brush (cell collecting device) for preserving a cell sample and comprising a pap unit.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to preserve cells utilizing the cell preservation fluid of Dunphy, Hurley and Harrison and to further incorporate the medium into a device for collecting and preserving cells as taught by Wainwright because the device of Wainwright was disclosed as useful in collecting and preserving cells in a container containing cell preservation fluid. Through the teachings of a cell preservation fluid by Dunphy, Hurley and Harrison, one of ordinary skill in the art would have been motivated to utilize the cell preservation fluid in the container of Wainwright to preserve cells because doing so would enable the skilled artisan to preserve cells for histological and cytological analysis of cells.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen C Siu whose telephone number is 703-308-7522. The examiner can normally be reached on M-F, 7:30-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M Woodward can be reached on 703-308-4028. The fax phone numbers

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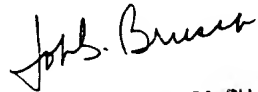
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for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Stephen Siu



JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER